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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 532552000102
INTERNATIONAL APPLICATION NO. PCT/US2004/011812		INTERNATIONAL FILING DATE 16 April 2004
TITLE OF INVENTION COMPOSITIONS FOR DELIVERY OF DRUG COMBINATIONS		PRIORITY DATE CLAIMED 16 April 2003
APPLICANT(S) FOR DO/EO/US Paul TARDI et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.		
2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.		
3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.		
4. <input type="checkbox"/> The US has been elected (Article 31).		
5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))		
a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> has been communicated by the International Bureau.		
c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).		
6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).		
a. <input type="checkbox"/> is attached hereto.		
b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).		
7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))		
a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> have been communicated by the International Bureau.		
c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.		
d. <input type="checkbox"/> have not been made and will not be made.		
8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).		
9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).		
10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11 to 20 below concern document(s) or information included:		
11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (3 pages)		
12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
13. <input type="checkbox"/> A preliminary amendment.		
14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.		
15. <input type="checkbox"/> A substitute specification.		
16. <input type="checkbox"/> A power of attorney and/or change of address letter.		
17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.		
18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).		
19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/553,373	INTERNATIONAL APPLICATION NO. PCT/US2004/011812	ATTORNEY'S DOCKET NUMBER 532552000102
20. <input checked="" type="checkbox"/> Other items or information: <div style="text-align: center; margin-top: 5px;"> PTO/SB/08a/b Form (1 page plus duplicate) References (6) Return Receipt Postcard </div>		
The following fees have been submitted		CALCULATIONS
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300		\$
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200		\$
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500		\$
TOTAL OF 21, 22 and 23 =		\$ 0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)
- 100 =	/50 =	x \$250.00
		\$
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	- 20 =	x
Independent claims	- 3 =	x
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ 360.00
TOTAL OF ABOVE CALCULATIONS =		\$ 0.00
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		0.00
SUBTOTAL =		\$ 0.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$
TOTAL NATIONAL FEE =		\$ 0.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +		\$
TOTAL FEES ENCLOSED =		\$ 0.00
		Amount to be refunded: \$
		Amount to be charged \$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ 0.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. ~~A duplicate copy of this sheet is enclosed.~~
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Kate H. Murashige
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
(858) 720-5112

CUSTOMER NUMBER: 25225

/Kate H. Murashige/
SIGNATURE

Kate H. Murashige
NAME

29,959
REGISTRATION NUMBER

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)
10/553,373

INTERNATIONAL APPLICATION NO.
PCT/US2004/011812

ATTORNEY'S DOCKET NUMBER
532552000102

I hereby certify that this paper is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EM 057522242 US, on the date shown below in an envelope addressed to: MS PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: August 7, 2007

Signature: Lenay Rogus (Lenay Rogus)

Please type a plus sign (+) inside this box 

PTO/SB/05 (03-01)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	532552000120
	First Inventor	Paul TARDI, et al.
	Title	COMPOSITIONS FOR DELIVERY OF DRUG COMBINATIONS
	Express Mail Label No.	EV 042154285 US

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO:
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1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17) <i>(Submit an original, and a duplicate for fee processing)</i> 2. <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. 3. <input checked="" type="checkbox"/> Specification [Total Pages 83] <i>(preferred arrangement set forth below)</i> - Descriptive title of the invention - Cross Reference to Related Applications - Statement Regarding Fed sponsored R & D - Reference to sequence listing, a table, or a computer program listing appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure 4. <input type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <input type="text"/> 5. Oath or Declaration [Total Pages <input type="text"/> a. <input type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) <i>(for continuation/divisional with Box 18 completed)</i> i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). 6. <input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76	7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) 8. <input type="checkbox"/> Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, all necessary)</i> a. <input type="checkbox"/> Computer Readable Form (CRF) b. Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> paper c. <input type="checkbox"/> Statements verifying identity of above copies ACCOMPANYING APPLICATIONS PARTS 9. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney <i>(when there is an assignee)</i> 11. <input type="checkbox"/> English Translation Document <i>(if applicable)</i> 12. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations 13. <input type="checkbox"/> Preliminary Amendment 14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) <i>(Should be specifically itemized)</i> 15. <input type="checkbox"/> Certified Copy of Priority Document(s) <i>(if foreign priority is claimed)</i> 16. <input type="checkbox"/> Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent. 17. <input type="checkbox"/> Other: <input type="text"/>
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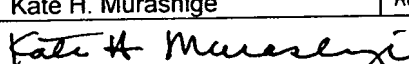
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No.: 10/264,538

Prior application information: Examiner To be assigned Group / Art Unit: 1614

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

<input checked="" type="checkbox"/> Customer Number or Bar Code Label	 25225	or <input checked="" type="checkbox"/> Correspondence address below
Name	Kate H. Murashige (29, 959) Morrison & Foerster LLP	
Address	3811 Valley Centre Drive, Suite 500	
City	San Diego	State California Zip Code 92130
Country	United States	Telephone (858) 720-5112 Fax (858) 720-5125
Name (Print/Type)	Kate H. Murashige	Registration No. (Attorney/Agent) 29,959
Signature		Date April 2, 2003

<h2 style="margin: 0;">FEE TRANSMITTAL</h2> <h3 style="margin: 0;">for FY 2003</h3> <p style="margin: 0; font-size: small;">Patent fees are subject to annual revision.</p>		Complete if Known	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	
		Filing Date	
		First Named Inventor	
		Examiner Name	
		Group Art Unit	
TOTAL AMOUNT OF PAYMENT		(\$)	
TOTAL AMOUNT OF PAYMENT (\$) 375.00		Attorney Docket No.	
		532552000120	

METHOD OF PAYMENT (check all that apply)		FEE CALCULATION (continued)																																																																																																																																																																																			
<input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> Other <input type="checkbox"/> None <input checked="" type="checkbox"/> Deposit Account Deposit Account Number: 03-1952 Deposit Account Name: Morrison & Foerster LLP The Commissioner is hereby authorized to: (check all that apply) <input checked="" type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) during the pendency of this application <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.		3. ADDITIONAL FEES <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr><td>1051</td><td>130</td><td>2051</td><td>65</td><td>Surcharge - late filing fee or oath</td><td></td></tr> <tr><td>1052</td><td>50</td><td>2052</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet.</td><td></td></tr> <tr><td>1053</td><td>130</td><td>1053</td><td>130</td><td>Non-English specification</td><td></td></tr> <tr><td>1812</td><td>2,520</td><td>1812</td><td>2,520</td><td>For filing a request for ex parte reexamination</td><td></td></tr> <tr><td>1804</td><td>920*</td><td>1804</td><td>920*</td><td>Requesting publication of SIR prior to Examiner action</td><td></td></tr> <tr><td>1805</td><td>1,840*</td><td>1805</td><td>1,840*</td><td>Requesting publication of SIR after Examiner action</td><td></td></tr> <tr><td>1251</td><td>110</td><td>2251</td><td>55</td><td>Extension for reply within first month</td><td></td></tr> <tr><td>1252</td><td>410</td><td>2252</td><td>205</td><td>Extension for reply within second month</td><td></td></tr> <tr><td>1253</td><td>930</td><td>2253</td><td>465</td><td>Extension for reply within third month</td><td></td></tr> <tr><td>1254</td><td>1,450</td><td>2254</td><td>725</td><td>Extension for reply within fourth month</td><td></td></tr> <tr><td>1255</td><td>1,970</td><td>2255</td><td>985</td><td>Extension for reply within fifth month</td><td></td></tr> <tr><td>1401</td><td>320</td><td>2401</td><td>160</td><td>Notice of Appeal</td><td></td></tr> <tr><td>1402</td><td>320</td><td>2402</td><td>160</td><td>Filing a brief in support of an appeal</td><td></td></tr> <tr><td>1403</td><td>280</td><td>2403</td><td>140</td><td>Request for oral hearing</td><td></td></tr> <tr><td>1451</td><td>1,510</td><td>1451</td><td>1,510</td><td>Petition to institute a public use proceeding</td><td></td></tr> <tr><td>1452</td><td>110</td><td>2452</td><td>55</td><td>Petition to revive - unavoidable</td><td></td></tr> <tr><td>1453</td><td>1,300</td><td>2453</td><td>650</td><td>Petition to revive - unintentional</td><td></td></tr> <tr><td>1501</td><td>1,300</td><td>2501</td><td>650</td><td>Utility issue fee (or reissue)</td><td></td></tr> <tr><td>1502</td><td>470</td><td>2502</td><td>235</td><td>Design issue fee</td><td></td></tr> <tr><td>1503</td><td>630</td><td>2503</td><td>315</td><td>Plant issue fee</td><td></td></tr> <tr><td>1460</td><td>130</td><td>1460</td><td>130</td><td>Petitions to the Commissioner</td><td></td></tr> <tr><td>1807</td><td>50</td><td>1807</td><td>50</td><td>Processing fee under 37 CFR 1.17(q)</td><td></td></tr> <tr><td>1806</td><td>180</td><td>1806</td><td>180</td><td>Submission of Information Disclosure Stmt</td><td></td></tr> <tr><td>8021</td><td>40</td><td>8021</td><td>40</td><td>Recording each patent assignment per property (times number of properties)</td><td></td></tr> <tr><td>1809</td><td>750</td><td>2809</td><td>375</td><td>Filing a submission after final rejection (37 CFR 1.129(a))</td><td></td></tr> <tr><td>1810</td><td>750</td><td>2810</td><td>375</td><td>For each additional invention to be examined (37CFR 1.129(b))</td><td></td></tr> <tr><td>1801</td><td>750</td><td>2801</td><td>375</td><td>Request for Continued Examination (RCE)</td><td></td></tr> <tr><td>1802</td><td>900</td><td>1802</td><td>900</td><td>Request for expedited examination of a design application</td><td></td></tr> </tbody> </table>		Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1051	130	2051	65	Surcharge - late filing fee or oath		1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.		1053	130	1053	130	Non-English specification		1812	2,520	1812	2,520	For filing a request for ex parte reexamination		1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action		1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action		1251	110	2251	55	Extension for reply within first month		1252	410	2252	205	Extension for reply within second month		1253	930	2253	465	Extension for reply within third month		1254	1,450	2254	725	Extension for reply within fourth month		1255	1,970	2255	985	Extension for reply within fifth month		1401	320	2401	160	Notice of Appeal		1402	320	2402	160	Filing a brief in support of an appeal		1403	280	2403	140	Request for oral hearing		1451	1,510	1451	1,510	Petition to institute a public use proceeding		1452	110	2452	55	Petition to revive - unavoidable		1453	1,300	2453	650	Petition to revive - unintentional		1501	1,300	2501	650	Utility issue fee (or reissue)		1502	470	2502	235	Design issue fee		1503	630	2503	315	Plant issue fee		1460	130	1460	130	Petitions to the Commissioner		1807	50	1807	50	Processing fee under 37 CFR 1.17(q)		1806	180	1806	180	Submission of Information Disclosure Stmt		8021	40	8021	40	Recording each patent assignment per property (times number of properties)		1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))		1810	750	2810	375	For each additional invention to be examined (37CFR 1.129(b))		1801	750	2801	375	Request for Continued Examination (RCE)		1802	900	1802	900	Request for expedited examination of a design application	
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SUBMITTED BY		Complete (if applicable)	
Name (Print/Type)	Kate H. Murashige	Registration No. (Attorney/Agent)	29,959
Signature		Telephone	(858) 720-5112
		Date	April 2, 2003

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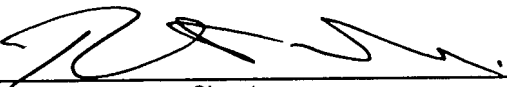
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Application Data Sheet